



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1903]

Modernizing Pharmaceutical Quality Systems; Studying Quality Metrics and Quality Culture; Quality Metrics Feedback Program; Reopening of Submission Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of submission period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the submission period for the notice entitled “Modernizing Pharmaceutical Quality Systems; Studying Quality Metrics and Quality Culture; Quality Metrics Feedback Program” that published in the *Federal Register* of June 29, 2018. The Agency is taking this action to allow interested persons additional time to participate in the program.

DATES: FDA is reopening the submission period for the notice published on June 29, 2018 (83 FR 30748). Submit written requests to participate in the program by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your participation in this program.

FOR FURTHER INFORMATION CONTACT: Tara Gooen Bizjak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6649, Silver Spring, MD 20993, 301-796-3257, [Tara.Gooen@fda.hhs.gov](mailto:Tara.Gooen@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In the *Federal Register* of June 29, 2018 (83 FR 30748), FDA published a notice with a 1-year and 30-day period to submit a request to participate in the “Modernizing Pharmaceutical Quality Systems; Studying Quality Metrics and Quality Culture;

Quality Metrics Feedback Program.” FDA is reopening the submission period until [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The Agency believes that an additional 120 days will allow adequate time for interested persons to participate without compromising the program.

To be considered for the program, a company should submit a statement of interest for participation to OPQ-OS-QualityMetrics@fda.hhs.gov. The statement of interest should include agreement to the selection qualities listed in 83 FR 30748 at 30749-30750, section III.A.

Dated: August 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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